UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,212	11/16/2001	Preeti Lal	PF-0221-3 DIV	9736

27904 7590 09/20/2002

INCYTE GENOMICS, INC.
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/20/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,212	Applicant(s) LAL ET AL.	
	Examiner David J. Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9,10,12-16,28,29,46-48,57 and 58* is/are pending in the application.

4a) Of the above claim(s) *1,14-16,28,29 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,9,10,12,13,46,48,57 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Comparison* .

DETAILED ACTION

Application Status

Claims 1, 3-7, 9, 10, 12-16, 28, 29, 46-48, and 57 are pending in the application.

Applicants' election with traverse of Group II, claims 3-7, 9, 10, 12, 13, 46, 48, and 57, amendment to claims 1, 3-5, 13, and 57, addition of claim 58, and cancellation of claim 11 in Paper No. 5, filed 07/02/02 is acknowledged.

Election/Restrictions

1. Applicants traverse the restriction requirement on the grounds that the claims of Groups IV-VII are methods of using the polynucleotides and microarrays of elected Group II and should be rejoined and co-examined with the claims of Group II. Applicants' argument is not found persuasive. If the claims of Group II are found to be allowable, then the claims of Groups IV-VI will be evaluated to determine if they are directed to processes of making or processes of using the patentable product, and if so would be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, In re Ochiai, and In re Brouwer). However, as the elected claims are not yet allowable, rejoinder is not as yet required.

Applicants further traverse the restriction requirement on the grounds that examination of the claim of Group I can be co-examined with the claims of Group II without an undue burden on the examiner. Applicants' argument is not found persuasive. Although the polynucleotide of Group II and the polypeptide of Group I are related, they are distinct inventions because the polypeptide can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, the polynucleotide of Group II can be used for processes other than the production of a polypeptide, such as nucleic acid hybridization assays. Therefore, Groups I and II are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 14-16, 28, 29, and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

1. It is noted that an Information Disclosure Statement (Form PTO-1449) has been filed with the instant application in Paper No. 1. However, citations 24 and 25 fail to comply with the requirements for an IDS. See 37 CFR 1.98 and MPEP § 609 regarding content of an IDS. Upon submission of an IDS in proper form, the examiner will consider the references and return Form PTO-1449 in a subsequent communication. Specifically, citations 24 and 25 fail to identify a database, e.g., GenBank or EMBL, from which the sequences can be accessed.

Specification/Informalities

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Polynucleotide Encoding a Human Sodium-Dependent Phosphate Cotransporter". See MPEP § 606.01.

Claim Objections

3. Claim 3, 12, 13, 57, and 58 are objected to because of the following informalities: the term "naturally occurring" is grammatically incorrect and should be replaced with, for example, "naturally-occurring". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 3-7, 9 10, 12, 13, 46, 48, 57, and 58 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 3-7, 9, and 10 are drawn to drawn to a polynucleotide encoding the polypeptide of SEQ ID NO:1 or variants and fragments thereof, the polynucleotide of SEQ ID NO:2, a recombinant polynucleotide, and a host cell. Claims 9 and 10 are drawn to a method of producing a polypeptide encoded by the polynucleotide of claim 3 or the polypeptide of SEQ ID NO:1. Claims 12, 13, 57, and 58 are drawn to the polynucleotide of SEQ ID NO:2, variants and fragments thereof as encompassed by the claims. Claim 46 is drawn to a microarray comprising the polynucleotide of claim 13. Claim 48 is drawn to an array comprising a nucleic acid comprising a polynucleotide completely complementary to at least 30 nucleotides of a polynucleotide of claim 12. Applicants assert at least one utility for the claimed isolated polynucleotide of SEQ ID NO:2 as useful in the expression of the polypeptide of SEQ ID NO:1 (page 14 of the instant specification), which is asserted to exhibit sodium-dependent phosphate transport activity based on 48 % homology with a human renal sodium phosphate transport protein and 29 % homology to a rat brain-specific sodium-dependent inorganic phosphate cotransporter (pages 10 and 11 of the instant specification). Other than the polynucleotide sequence as set forth in SEQ ID NO:2 and the amino acid sequence encoded thereby as set forth in SEQ ID NO:1, the specification provides no functional characterization of this polynucleotide. The prior art teaches that homologous proteins having significant sequence homology may exhibit different functions. For example, van de Loo et al. (*Proc Natl Acad Sci USA* 92:6743-6747, 1995) teach that two polypeptides sharing 67 % homology have different functions – one polypeptide exhibits hydroxylase activity, while the other exhibits desaturase activity. Also, Seffernick et al. (*J Bacteriol* 183:2405-2410, 2001) teach that two polypeptides sharing 98 % homology have different functions – one polypeptide exhibits deaminase activity, while the other exhibits chlorohydrolase activity. Seffernick et al. also teach that current genome annotation (predicting protein function based on sequence identity) efforts consider >50% identity to be reasonably sound (page 2409), and as described above, SEQ ID NO:2 shares less than 50 % identity with either human renal sodium phosphate transport protein or rat brain-specific sodium-dependent inorganic phosphate cotransporter. Additionally, Bork (Genome Res 10:398-400, 2000) teaches that gene annotation, i.e., predicting the function of a polypeptide encoded by a specific gene, by sequence database searches has a considerable error rate

(page 399) and that as errors accumulate and propagate, it becomes more difficult to infer the correct function of an encoded polypeptide from the many possibilities revealed by a database search (page 399). Therefore one of ordinary skill in the art would recognize that, while a polypeptide's function can be predicted with a high degree of uncertainty by gene annotation, particularly with such low homology as is the instant case, the function of the polypeptide must be determined empirically. As stated above, no characterization, other than the disclosure of the amino acid sequence of SEQ ID NO:1, has been provided. Determination of the function of the polypeptide encoded by the claimed polynucleotides would require or constitute performing additional research. See Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Thus, the asserted utility of the claimed polynucleotides, fragments, and variants thereof as encompassed by the claims is not substantial or specific.

Applicants also assert at least one utility for the claimed array or microarray as useful in the diagnosis of disorders that are associated with expression of NAPTR (pages 31 and 32). However, the specification provides no information linking the polynucleotide of SEQ ID NO:2 or the polypeptide of SEQ ID NO:1 to any **specific** disease state that could be diagnosed using the claimed array or microarray. Thus, the asserted utility of the claimed array or microarray is not substantial or specific.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10, 12, 13, 48, 57, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 10 is indefinite in the recitation of "[a] method of claim 9". It is suggested that the term be replaced with, for example, "[t]he method of claim 9".

7. Claims 12 (claim 48 dependent therefrom), 13 (claim 46 dependent therefrom), 57, and 58 are indefinite in the recitation of "a polynucleotide complementary to a polynucleotide" in parts c) and d) of the claims. It is noted that the specification provides a definition for the term "complementary" at page 7 of the specification. However, it is unclear from this definition as to whether the complementary strand is a partial or complete complement. It is suggested that applicants clarify their meaning of the term "complementary" with, for example, "a polynucleotide completely complementary to a polynucleotide".

8. Claim 48 is confusing in the recitation of "nucleotide molecules... ...comprises a first oligonucleotide". It is unclear as to how a nucleotide can comprise an oligonucleotide. It is suggested that applicants replace the term "nucleotide molecules" with, for example, "nucleic acid molecules".

9. Claim 48 is indefinite in the recitation of "specifically hybridizable" in line 3. Neither the specification nor the claims provides a definition for the term "specifically hybridizable" and it is unclear as to how complementary a polynucleotide must be to be "specifically hybridizable with at least 30 contiguous nucleotides of a target polynucleotide". It is suggested that the term "specifically hybridizable" be replaced with, for example, "completely complementary".

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3, 6, 7, 9, 12, 13, 46, 48, 57, and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 parts b) and d) (claims 6, 7, and 9 dependent therefrom) are drawn to a genus of polynucleotides encoding either a polypeptide comprising a naturally-occurring amino acid sequence that

is at least 90 % identical to SEQ ID NO:1 or an immunogenic fragment of SEQ ID NO:1, respectively, that have not been fully described in the specification. Claim 12 parts b), d), and e) are drawn to a genus of polynucleotides comprising a naturally-occurring polynucleotide that is at least 90 % identical to SEQ ID NO:2, complements thereof, and RNA equivalents thereof, respectively, that have not been fully described in the specification. Claim 13 (claim 46 dependent therefrom) is drawn to a genus of polynucleotides comprising at least 20 contiguous nucleotides of: SEQ ID NO:2 or a complement thereof, a naturally-occurring polynucleotide that is at least 90 % identical to SEQ ID NO:2 or a complement thereof, and RNA equivalents thereof, that have not been fully described in the specification. Claim 48 is drawn to an array comprising a genus of nucleic acid molecules comprising a first oligo or polynucleotide that specifically hybridizes with at least 30 contiguous nucleotides of a target polynucleotide of claim 12 that have not been fully described in the specification. Claim 57 parts b), d), and e) are drawn to a genus of polynucleotides comprising a naturally-occurring polynucleotide that is at least 95 % identical to SEQ ID NO:2, complements thereof, and RNA equivalents thereof, respectively, that have not been fully described in the specification. Claim 58 is drawn to a genus of polynucleotides comprising at least 60 contiguous nucleotides of: SEQ ID NO:2 or a complement thereof, a naturally-occurring polynucleotide that is at least 90 % identical to SEQ ID NO:2 or a complement thereof, and RNA equivalents thereof, that have not been fully described in the specification.

The specification does not disclosure the function of all polynucleotide sequences as described above. The genus of polynucleotides as described above is a large variable genus with the potentiality of encoding proteins with functions other than the disclosed sodium-dependent transport of phosphate. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims, including fragments and partial polynucleotide sequences. The specification discloses only a single species of the claimed genus, i.e., SEQ ID NO:2 encoding SEQ ID NO:1, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

Additionally, regarding claims 3, 12, 13, 57, and 58, the specification defines an "allelic sequence" (see page 12 of the instant specification) as an alternative form of the gene which may result

in at least one mutation in the nucleic acid sequence. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. This definition does not provide any specific information about the structure of naturally occurring (alleles) variants of SEQ ID NO:2 (i.e., where are the regions within which mutations are likely to occur) nor discloses any function for naturally occurring variants. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO:2 relates to the structure of any naturally occuring alleles. The general knowledge in the art concerning alleles dose not provide any indication of how one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art structure of one does not provide guidance to the structure of others. The genus of nucleic acids that comprise the claimed polynucleotides is a large variable genus with potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus (i.e the sequence encoding SEQ ID NO:2) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

11. Claim 3, 6, 7, 9, 12, 13, 46, 48, 57, and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for *all* polynucleotides encoding either a polypeptide comprising a naturally-occurring amino acid sequence that is at least 90 % identical to SEQ ID NO:1 or an immunogenic fragment of SEQ ID NO:1, respectively, (claim 3), *all* polynucleotides comprising a naturally-occurring polynucleotide that is at least 90 % identical to SEQ ID NO:2, complements thereof, and RNA equivalents thereof, respectively (claim 12), *all* polynucleotides comprising at least 20 or 60 contiguous nucleotides of: SEQ ID NO:2 or a complement thereof, a naturally-occurring polynucleotide that is at least 90 % identical to SEQ ID NO:2 or a complement thereof, and RNA equivalents thereof (claims 13 and 58), an array comprising *all* nucleic acid molecules comprising a first oligo or polynucleotide that specifically hybridizes with at least 30

contiguous nucleotides of a target polynucleotide of claim 12 (claim 48), and *all* polynucleotides comprising a naturally-occurring polynucleotide that is at least 95 % identical to SEQ ID NO:2, complements thereof, and RNA equivalents thereof, respectively (claim 57). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claim 3 (claims 6, 7, and 9 dependent therefrom), 12, 13 (claim 46 dependent therefrom), 48, 57 and 58 are so broad as to encompass any polynucleotide or array comprising any polynucleotide as described above. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the polynucleotide sequence determines a proteins structural and functional properties, predictability of which changes in an encoding polynucleotide can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity (in this case sodium-dependent transport of phosphate) requires a knowledge of and guidance with regard to which amino acids of the encoded protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to SEQ ID NO:2. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple nucleotide substitutions or multiple modifications, as encompassed by the instant claims, and the positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining a polypeptide with the desired activity/utility are limited and the result of such

modifications is unpredictable. The prior art teaches that modifications to an encoding nucleic acid, even minor modifications, may completely alter the function of the encoded protein sequence. As a representative example, Broun et al. (*Science* 282:1315-1317, 1998) teach that as few as four amino acid substitutions in a polypeptide having approximately 380 amino acids completely alters the enzymatic function of the polypeptide from a desaturase to a hydroxylase (see abstract). In addition, one skilled in the art would expect any tolerance to modification for a given encoded protein to diminish with each further and additional modification, e.g. multiple substitutions. Furthermore, the prior art teaches that two polypeptides encoded by naturally-occurring polynucleotides, while sharing significant sequence homology, may have completely different functions. As a representative example, Seffernick et al. (*J Bacteriol* 183:2405-2410) teach that, while *Pseudomonas* melamine deaminase and atrazine chlorohydrolase differ at only 9 amino acids out of 475 and share greater than 98 % homology, the two enzymes catalyze completely different reactions, i.e., deamination and dechloronation, and neither enzyme had activity on the others' substrates. Seffernick et al. also teaches that a reasonable threshold for predicting protein function by gene annotation is greater than 50 % sequence identity, however, Seffernick et al. also comment that their results cast doubt on this observation (page 2409), suggesting that the threshold may be much higher. Also, as stated above, Bork (Genome Res 10:398-400, 2000) teaches that gene annotation, i.e., predicting the function of a polypeptide encoded by a specific gene, by sequence database searches has a considerable error rate (page 399) and that as errors accumulate and propagate, it becomes more difficult to infer the correct function of an encoded polypeptide from the many possibilities revealed by a database search (page 399).

The specification does not support the broad scope of the claims which encompass all polynucleotides and arrays comprising polynucleotides as described above because the specification does not establish: (A) regions of the nucleic acid structure which may be modified without affecting the encoded polypeptide activity; (B) the general tolerance of SEQ ID NO:2 to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues of SEQ ID NO:2 with an

expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all polynucleotides and arrays comprising all polynucleotides as described above. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re* Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re* Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 3, 13, and 58 are rejected under 35 U.S.C. 102(a) as being anticipated by Gasparini (IDS reference 18 of Paper No. 1; GenBank Accession Number Z83593). Claim 3 is drawn to a polynucleotide encoding a polypeptide selected from: SEQ ID NO:1, a polypeptide comprising a naturally-occurring amino acid sequence that is at least 90 % identical to SEQ ID NO:1, a fragment of SEQ ID NO:1 with phosphate transport ability, or an immunogenic fragment of SEQ ID NO:1. Claims 13 and 58 are drawn to a polynucleotide comprising at least 20 or 60 contiguou s nucleotides of a polynucleotide selected from: a polynucleotide comprising SEQ ID NO:2 or a complement thereof, a polynucleotide comprising a naturally-occurring nucleic acid sequence that is at least 90 % identical to SEQ ID NO:2 or a complement thereof, and RNA equivalents thereof. Gasparini teaches a polynucleotide encoding amino acids 96 to 193 of SEQ ID NO:1 and would anticipate claim 3 part d) as being an immunogenic fragment (as described in

the specification at page 42 as typically being 15 residues in length) of SEQ ID NO:1. The polynucleotide of Gasparini is 100 % identical to nucleotides 519 to 814 of SEQ ID NO:2 and would anticipate part a) of claims 13 and 58. Therefore, this anticipates claims 3, 13, and 58 as written. See attached sequence comparisons for details.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-7, 9, 10, 12, and 57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,985,604 (hereinafter referred to as '604). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ

645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because: claims 3 and 4 of the application are generic to all that is recited in claims 1 and 2 of the patent, claim 5 of the application is generic to all that is recited in claim 3 of the patent, claim 6 of the application is generic to all that is recited in claim 6 of the patent, claim 7 of the application is generic to all that is recited in claim 7 of the patent, claims 9 and 10 of the application are generic to all that is recited in claim 8 of the patent, claims 12 and 57 of the application are generic to all that is recited in claims 4 and 5 of the patent. That is, claims 1 and 2, 3, 6, 7, 8, and 4 and 5 fall entirely within the scope of claims 3 and 4, 5, 6, 7, 9 and 10, and 12 and 57, respectively, of the application. Thus the claims of the patent anticipate the claims of the instant application.

Conclusion

14. All claims are rejected. No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600